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8 **IN THE UNITED STATES DISTRICT COURT**
9 **FOR THE CENTRAL DISTRICT OF CALIFORNIA**
10 **WESTERN DIVISION**

11 EDWARD PEÑA, *individually and*
12 *on behalf of persons similarly*
situated,

13 *Plaintiff,*

14 v.

15 INTERNATIONAL MEDICAL
16 DEVICES, INC., MENOVA
INTERNATIONAL, INC.,
17 GESIVA MEDICAL, LLC, JAMES
J. ELIST, M.D., A MEDICAL
18 CORPORATION, AND DR.
JAMES ELIST,
19

20 *Defendants*

Case No. 2:22-cv-03391-SSS (PLAx)

PLAINTIFF'S RESPONSE TO
MOTION TO DISMISS
EQUITABLE CLAIMS IN
SECOND AMENDED
COMPLAINT

Date: April 14, 2023

Time: 2:00 pm

Crtm: 2 (via Zoom video conference)

Judge: Hon. Sunshine S. Sykes

I. INTRODUCTION

Because Plaintiff has corrected the deficiency that this Court identified in his prior pleadings by amending his complaint to plead that legal remedies are inadequate and that an actual and imminent threat of future harm exists, this Court should deny Defendants' Motion to Dismiss Plaintiff's Second Amended Complaint. *Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956, 969 (9th Cir. 2018). The Court previously denied Defendants' Motion to Dismiss Plaintiff's First Amended Complaint as to Plaintiff's legal claims but dismissed Plaintiff's claims for equitable relief without prejudice and granted leave to amend with respect to the equitable relief claims. (Dkt. 50 at 13.) Regarding the equitable relief claims, the Court observed that "the FAC does not plead that legal remedies are inadequate," (*Id.* at 11), and also that the allegation of "a 'possibility' that Plaintiff and the Class members would purchase the Penuma device and procedure in the future is insufficient to confer standing to pursue injunctive relief." (*Id.*) Plaintiff has now amended his pleading to allege that:

1. "If the Penuma device and procedure were redesigned to be safe and effective for cosmetic penile enlargement, FDA-cleared for this use, and truthfully marketed, Plaintiff would purchase a Penuma device and procedure in the future." (Dkt. 51 ¶ 69.)
2. Plaintiff and the Class members have suffered irreparable injury, and damages are not an adequate remedy for threatened future harm, because the Penuma surgery violates their bodily integrity and creates a substantial risk of permanent injury. (*Id.*)

As the Ninth Circuit has held, assuming the truth of well-pleaded facts on a motion to dismiss, "plausible allegations that [the plaintiff] might purchase the product in the future, despite the fact that it was once marred by false advertising or labeling" are sufficient to allege "an 'actual and imminent, not conjectural or hypothetical'

1 threat of future harm.” *Davidson*, 889 F.3d at 969. The Court should therefore deny
2 Defendants’ motion.

3 II. STANDARD OF REVIEW

4 On a motion to dismiss under Rule 12(b)(6), the Court must “accept the
5 complaint’s well-pleaded factual allegations as true, and construe all inferences in
6 the plaintiff’s favor.” *Ariz. Students’ Ass’n v. Ariz. Bd. of Regents*, 824 F.3d 858,
7 864 (9th Cir. 2016); *see also Eclectic Props. E, LLC v. Marcus & Millichap Co.*,
8 751 F.3d 990, 996 (9th Cir. 2014) (holding that “a court should ‘assume the[]
9 veracity’ of ‘well pleaded factual allegations’ and ‘determine whether they plausibly
10 give rise to an entitlement to relief’”) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 664
11 (2009)); *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 946 (9th
12 Cir. 2005) (“A claim should be dismissed only if it appears beyond doubt that the
13 plaintiff can establish no set of facts under which relief could be granted.”).

14 III. ARGUMENT AND AUTHORITIES

15 A. Plaintiff has pled a real and immediate threat of repeated injury.

16 Plaintiff’s Second Amended Complaint alleges that “Plaintiff continues to
17 desire a safe, effective penile implant. If the Penuma device and procedure were
18 redesigned to be safe and effective for cosmetic penile enlargement, FDA-cleared
19 for this use, and truthfully marketed, Plaintiff would purchase a Penuma device and
20 procedure in the future.”¹

21 As the Ninth Circuit has held, “plausible allegations that [the plaintiff] might
22 purchase the product in the future, despite the fact that it was once marred by false
23 advertising or labeling” are sufficient to allege “an ‘actual and imminent, not
24 conjectural or hypothetical’ threat of future harm.” *Davidson*, 889 F.3d at 969.

25
26 ¹ Contrary to Defendants’ accusation, Plaintiff has not “changed his mind,” (Dkt. 53 at 9), since
27 the filing of his First Amended Complaint, but rather stated more precisely, in light of the Court’s
28 Order granting him leave to amend to re-plead his claims for equitable relief, what he would do if
Penuma were redesigned to be safe and effective, FDA-cleared, and truthfully marketed.

1 Defendants' contention that this threat is not sufficiently "imminent" to warrant
 2 injunctive relief, (Dkt. 53 at 11), flies directly in the face of the Ninth Circuit's
 3 holding in *Davidson*:

4 We hold that a previously deceived consumer may have
 5 standing to seek an injunction against false advertising or
 6 labeling, even though the consumer now knows or
 7 suspects that the advertising was false at the time of the
 original purchase, because the consumer may suffer an
 "actual and imminent, not conjectural or hypothetical"
 threat of future harm.

8 *Davidson*, 889 F.3d at 969. Indeed, as Defendants acknowledge, (Dkt. 53 at 10),
 9 Plaintiff's allegations exactly track the allegations that the Ninth Circuit held are
 10 sufficient to show an imminent threat of future harm in *Davidson*. *See Davidson*,
 11 889 F.3d at 969–70. Contrary to Defendants' assertion, (Dkt. 53 at 9), Plaintiff's
 12 alternative pleading that he and other Class members also face a threat that "Plaintiff
 13 and the Class members will be unable to rely on Penuma's advertising or labeling in
 14 the future, and so will not purchase a Penuma device or procedure although they
 15 would like to," (Dkt. 51 ¶ 69), does not contradict the threatened harm that they will
 16 purchase a product they "reasonably, but incorrectly, assume" to be improved.
 17 *Davidson*, 889 F.3d at 970. The fact that alternative plausible threats of future harm
 18 exist in this case does not make the harm any less imminent, but rather speaks to the
 19 large number of Class members and the fact that this case remains at the pleading
 20 stage. *Unigestion Holding, S.A. v. UPM Tech., Inc.*, 160 F. Supp. 3d 1214, 1231 (D.
 21 Or. 2016) ("Under Fed. R. Civ. P. 8(d)(2), '[i]f a party makes alternative statements,
 22 the pleading is sufficient if any one of them is sufficient.'"); *see also Maisel v. S.C.*
 23 *Johnson & Son, Inc.*, No. 21-cv-00413, 2021 WL 1788397, at *12 (N.D. Cal. May
 24 5, 2021) (allowing alternative theories of relief at the pleading stage).

25 In a perfect world, perhaps, no one once deceived would ever allow himself
 26 to be deceived again. In the real world, however, as *Davidson* recognized, repeated
 27 deceptions can happen to reasonable people. *Davidson*, 889 F.3d at 969

1 (“Knowledge that the advertisement or label was false in the past does not equate to
 2 knowledge that it will remain false in the future.”) Plaintiff’s allegations of an
 3 imminent threat of future harm are particularly plausible in this case because
 4 Defendant Dr. Elist is a medical doctor. As a physician, Dr. Elist’s statements carry
 5 a greater weight and authority with the public than statements of an ordinary
 6 advertiser. A reasonable person would not automatically disbelieve assurances from
 7 a licensed physician—who has taken the Hippocratic oath—that a redesigned
 8 implant is safe and effective. Indeed, as alleged in Plaintiff’s Second Amended
 9 Complaint, Plaintiff’s counsel’s investigation has already revealed that “multiple
 10 men have paid Dr. Elist for repeated procedures based on misrepresentations that
 11 their initial poor results were unusual and that subsequent procedures would improve
 12 the results.” (Dkt. 51 ¶ 69.) To protect Plaintiff and others from reasonably, but
 13 incorrectly relying on Dr. Elist’s false statements about Penuma in the future as these
 14 men did, the Court should hold that Plaintiff has met *Davidson’s* requirements to
 15 plead actual and imminent harm.

16 **B. Plaintiff has pled a lack of adequate legal remedy.**

17 Because no amount of money can undo the harm of having one’s body scarred
 18 and disfigured, the Court should also reject Defendants’ argument that Plaintiff has
 19 failed to plead irreparable injury. Plaintiff’s Second Amended Complaint alleges that
 20 “Penuma’s design results in patients’ erect penises becoming *shorter* in most cases
 21 and in many cases disfigured,” (Dkt. 51 ¶ 36), and that “Plaintiff and the Class
 22 members have no adequate legal remedy.” (Dkt. 51 ¶ 69.) Defendants’
 23 misrepresentations caused irreparable injury because Plaintiff’s and the Class
 24 members’ “bodily integrity has been violated, creating a substantial risk of
 25 permanent injury.” (*Id.*)

26 As the Supreme Court has held, “[n]o right is held more sacred, or is more
 27 carefully guarded, by the common law, than the right of every individual to the
 28

possession and control of his own person.” *Cruzan v. Missouri Dep’t of Health*, 497 U.S. 261, 269 (1990). By performing surgery on Plaintiff and the Class members without informing them of the true risks, leaving their bodies seriously and in many cases permanently injured, Defendants have violated this core individual right. *See id.* (“This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment.”) If this injury is repeated, a suit for damages would be entirely inadequate relief. *See In re Meta Pixel Healthcare Litig.*, ___ F. Supp. 3d ___, 2022 WL 17869218, at *17 (N.D. Cal. December 22, 2022) (holding that privacy violation from disclosure of medical information “is precisely the kind of intangible injury that cannot be remedied by damages”); *see also Cyiark v. City of Houston*, 976 F. Supp. 591, 594 (S.D. Tex. 1996) (holding that “[t]he extended delay inherent in litigation, the difficulty of finding counsel, and the likelihood of miniscule damages demonstrate that Plaintiff has no viable legal remedy” against threatened future offensive conduct). This Court should therefore find that Plaintiff has pled a lack of adequate legal remedy and allow Plaintiff to pursue his equitable and legal remedies in the alternative. *Maisel*, 2021 WL 1788397, at *12 (“[T]he Court follows other courts in this district that find no bar to the pursuit of alternative remedies at the pleadings stage.”)

IV. CONCLUSION

Because Plaintiff’s Second Amended Complaint pleads a claim for equitable relief, the Court should deny Defendants’ Motion to Dismiss.

1 Dated: February 24, 2023

Respectfully submitted,

3 By: /s/ Michael A. Caddell

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